REMARKS

The Office Action dated November 23, 2004 has been received and carefully studied.

The Examiner states that the Information Disclosure Statement filed 3/12/02 contains two WO documents that are in Japanese and German, and that both documents have been considered to the extent that the Examiner could understand. Applicants note that the Information Disclosure Statement was filed in compliance with 37 C.F.R. 1.97 and 1.98 (the ISR is of record indicating the degree of relevance found by a foreign Patent Office), and thus the Examiner has an obligation to consider all of the information in full. See MPEP 609.

The Examiner rejects claims 1-5 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner objects to the term "under a stringent condition" for the reasons that it is impossible to determine when such conditions are met.

The rejection is respectfully traversed.

Applicants respectfully submit that those skilled in the art will be able to determine what constitutes stringent conditions. Reference is made to the paragraph in the specification bridging pages 10 and 11, where suitable stringent conditions are disclosed.

The Examiner also rejects claims 1-5 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that only

isolated nucleic acid comprising SEQ ID NO 1 and 2 meets the written description requirement, not the full breadth of the claims, since the claims read on the entire p51 gene comprising SEQ ID NO 2 and a native enhancer region controlling the transcription of the coding region.

By the accompanying amendment, claim 1 has been limited to an isolated gene encoding the p51 promoter region shown in DNA that encodes the p51 promoter region having the base sequence as set forth in SEQ ID NO: 1, and DNA that hybridizes to the base sequence set forth in SEQ ID NO: 1. It is believed that the amendment overcomes the rejection.

The Examiner rejects claims 1, 2 and 5 under 35 U.S.C. §101 as directed to non-statutory subject matter. By the accompanying amendment, claim 1 has been amended to recite an isolated gene. It is believed that the amendment overcome the rejection.

The Examiner rejects claims 1-5 under 35 U.S.C. §102(b) as being anticipated by GenBank Acc. No. AQ168656. The Examiner states that since the claims are broadly interpreted as being drawn to a nucleic acid sequence with various degrees of sequence similarity to either SEQ ID NO: 1 or 2, or to a specific portion of SEQ ID NO: 2, where the nucleic acid has p51 promoter activity, or an undefined activity of the specific portion of SEQ ID NO:2, wherein a recombinant plasmid, a transformant and a nucleic acid are claimed, such claims read on the cited reference which

teaches a nucleic acid with 90.6% similarity to nucleotide #672 to 1171 to the instant SEQ ID NO:2, and also teaches that the clone is in plasmid vector pBeloAAC11, which is a BAC clone in E. coli strain DH10B.

By the accompanying amendment, claim 1 has been amended so that it is directed only to the sequence of SEQ ID NO: 1, and claim 2 has been cancelled. In addition, GenBank Acc. No. AQ168656 does not contain TATA box, which exists in SEQ ID NO: 1 and which is needed for the p51 promoter activity. In this regard, reference is made to the specification at page 8, lines 13-17, where the TATA box of the sequence of SEQ ID NO: 1 is explained in detail.

The Examiner also rejects claims 1, 2 and 5 under 35 U.S.C. §102(b) as being anticipated by Yang et al. Yang et al. is cited for its disclosure in Figure 2A of a genomic structure of p63 gene encoding at least six different splicing variants. The Examiner takes the position that the p51 gene is the same as p63 gene because GenBank Acc. No. AF-124528 teaches that the C-terminal end of the instant SEQ ID NO: 2 is exon 1 of p63, absent evidence to the contrary.

Although GenBank Acc. No. AF124528 teaches nucleotides #5462-#5962 of SEQ ID NO:1, it does not teach the p51 promoter sequence of SEQ ID:1. Furthermore, this reference was published on January 4, 2001, well after the filing date of June 28, 2000 of the PCT application on which the instant application is based. Accordingly, it is not a reference against this case.

Yang et al. disclose a genomic structure of p63 gene in Figure 2A. However, Yang et al. do not disclose any of the DNA sequence, nor do Yang et al. disclose the p51 promoter sequence of SEQ ID NO:1.

Applicants also note that the experimental data in Example 1 of the specification demonstrate that the sequence of SEQ ID NO:1 exhibits the p51 promoter activity. Thus, the present invention has, for the first time, succeeded in sequencing the p51 promoter and confirmed the promoter activity thereof. Accordingly, it is believed that the present invention as now claimed is patentable over the cited references.

Reconsideration and allowance are respectfully requested in view of the foregoing.

Respectfully submitted,

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